

**REMARKS**

Claims 15 and 18 have been amended and claims 24-27 have been added to define preferred embodiments of the invention. The above amendments to the claims have been made to put the application in better condition for allowance. No new matter has been added.

Rejections under 35 U.S.C. § 112

Claim 15 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner states that the phrase "soluble, emulsifiable, dispersible, optionally low molecular weight, optionally biodegradable, and/or optionally bioadhesive organic oligomer or polymer formulated as a composition optionally forming a lubricant film or acting as a lubricant" is unclear. Applicants submit that claim 15 has been amended to delete the above recitation and to replace it with the phrase "natural, modified natural, or synthetic polymers." Support for this amendment can be found on page 6, line 22 of the specification.

Claim 18 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner states that the recitation wherein the composition is in the form of a solution, emulsion, dispersion, or oil is indefinite because claim 12 is limited to a "paste, gel, cream, suppository, or foam." Applicants submit that claim 18 has been amended to delete the phrase, thus rendering the rejection moot.

Thus, Applicants submit that the rejections under 112 have been obviated by deleting the rejected language from claims 15 and 18. Applicants respectfully request that the rejections be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 12, 13, 15, 16, and 18-22 were rejected under 35 U.S.C. §103(a) as being obvious over Van Leuven (U.S. 4,267,168) in view of Bringloe (U.S. 4,765,478). The Examiner asserts that Van Leuven discloses a composition which is useful as a lubricant (i.e. glycerin- see col. 6, lines 1-7) to be used during delivery at the time of birth (col. 6, lines 52 to 54) and does not contain alkali metal salts of metaphosphates (col. 6, lines 26 to 36). The Examiner acknowledges that Van Leuven does not disclose that the composition is in the form of a gel, but cites Bringloe as disclosing that hydroxymethyl cellulose is a known gelling agent in topical compositions. Applicants respectfully disagree.

Van Leuven discloses a liquid biocidal composition comprising dodecyl benzene sulfonic acid or a water soluble salt thereof, lauryldiethanol amide, triethanol amine, propylene glycol, glycerol, sodium polypectate, silver ions, ammonium hydroxide and distilled water. The composition exhibits pH in the range of from about 7.2 to about 7.8 and can be used, inter alia, as a lubricant for manual examination during labor and for assistance during delivery.

Bringloe is directed to a dispenser for a medicament contained in a viscous pharmaceutically acceptable carrier and more particularly to a dispenser that comprises a tray containing a support layer upon which lies the pharmaceutically acceptable carrier. The composition may be in the form of an aqueous gel, with suitable gelling

agents comprising, inter alia, cellulose derivatives such as carboxymethyl cellulose and hydroxymethyl cellulose. Applicants submit that the combination of Bringloe and Van Leuven is improper for the foregoing reasons.

Firstly, Bringloe does not relate to human vaginal childbirth or to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother. Thus, a person skilled in the art would not be motivated to combine these two references relating to completely different subject matter.

Further, although it has long been known to use cellulose derivatives as thickeners, this recitation in Bringloe does not cure the deficiencies of Van Leuven. In fact, it is clear from the disclosure on lines 9-16, col. 6 of Van Leuven that pH is maintained between 7.2 and 7.8 and it is very important to maintain this pH to avoid gelling of polypectate. Clearly, gelling is undesirable and Van Leuven seeks to maintain the liquid characteristic of the composition.

Finally, Van Leuven discloses that the addition of inert thickeners (e.g. hydroxymethyl cellulose) will “not alter the basic characteristics of the *liquid* biocidal composition” (emphasis added, cf. col. 6, lines 62-68 of Van Leuven).

Thus, Applicants submit that Bringloe does not cure the deficiencies of Van Leuven because Van Leuven teaches against allowing the composition to gel or changes in the characteristics of the liquid biocidal composition. The addition of inert thickeners such as hydroxymethyl cellulose as mentioned in Bringloe do not change this requirement of Van Leuven. Therefore, based on the above reasoning, Applicants submit that the combination of Van Leuven and Bringloe do not render obvious the subject matter of claims 12, 13, 15, 16, and 18-22.

Claim 14 was rejected under 35 U.S.C. §103(a) as being obvious over Van Leuven (U.S. 4,267,168) in view of Bringloe (U.S. 4,765,478), and further in view of Hardy (U.S. 4,981,686). The Examiner asserts that Hardy discloses lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol, thus it would have been obvious to add a natural or synthetic oil, fat or wax to the composition taught by the combination of Van Leuven and Bringloe with Hardy. Applicants submit that Bringloe does not cure the deficiencies of Van Leuven and no combination of Van Leuven and Bringloe, or Van Leuven, Bringloe, and Hardy renders obvious the features of independent claim 12. Thus, the combination of Van Leuven, Bringloe, and Hardy does not render obvious all of the features of claim 14 which depends from claim 12. Applicants request that the rejection of claim 14 be withdrawn.

Claims 12, 13, 15, 16, 18-20 and 22 have been rejected under 35 U.S.C. §103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Bringloe (U.S. 4,765,478). The Examiner asserts that Kasahara discloses a compositing comprising a physiologically acceptable organic lubricant and no alkali metal salts of metaphosphates, optionally containing carboxymethyl cellulose, into the birth canal of a woman (see col. 5, lines 16-51). Kasahara does not disclose a composition for reducing the frictional force between an item to be delivered and the birth canal of the mother, which is in the form of a paste, a gel, a cream, a suppository, or a foam. Bringloe does not relate to human vaginal childbirth or to a method for reducing the frictional force between an item to be delivered and the birth canal of the mother. Thus, a person skilled in the art would not be motivated to combine these two references

relating to completely different subject matter. Further, one skilled in the art would not find any teaching in Kasahara that would cause him to not provide the composition of Kasahara in the form of a liquid. Kasahara discloses that the composition is an aqueous solution (cf. col. 5, lines 7-50) and does not change its consistency even when adding further compounds such as carboxymethyl cellulose (cf. col. 5, lines 39-42). Further, it is important to account for the disclosure of Kasahara according to which the aqueous solution is difficult to use due to a too high viscosity if the content of solids is more than 15% (cf. col.5, lines 10-15). Because the composition suggested for use in human delivery in Kasahara only contains the solid product in an amount of 1% by weight (col. 5, lines 21-32), Kasahara teaches that the composition for human delivery be in the form of an aqueous solution even in the presence of thickeners such as carboxymethyl cellulose, and teaches away from the presently claimed method by teaching that a viscous composition is undesirable and counterproductive.

Claim 14 was rejected under 35 U.S.C. §103(a) as being obvious over Kasahara in view of Bringloe, and further in view of Hardy. The Examiner asserts that Hardy discloses lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol, thus it would have been obvious to add a natural or synthetic oil, fat or wax to the composition taught by the combination of Kasahara and Bringloe with Hardy. Applicants submit that no combination of Kasahara and Bringloe, or Kasahara, Bringloe, and Hardy renders obvious the features of independent claim 12 based on the reasoning above. Thus, the combination of Kasahara, Bringloe, and Hardy does not

render obvious all of the features of claim 14 which depends from claim 12. Applicants request that the rejection of claim 14 be withdrawn.

Claim 21 was rejected under 35 U.S.C. §103(a) as being obvious over Kasahara in view of Bringloe, and further in view of Van Leuven. The Examiner asserts that Kasahara discloses that the composition may contain an antiseptic but is silent as to the amount of antiseptic. Applicants submit that no combination of Kasahara and Bringloe, or Kasahara, Bringloe, and Van Leuven renders obvious the features of independent claim 12 based on the reasoning above. Thus, the combination of Kasahara, Bringloe, and Van Leuven does not render obvious all of the features of claim 21 which depends from claim 12. Applicants request that the rejection of claim 21 be withdrawn.

Claim 23 has been rejected under 35 U.S.C. §103(a) as being obvious over Kasahara in view of Bringloe, and further in view of JP46-24256 (JP '256). The Examiner asserts that Kasahara discloses applying a composition to the birth canal to ease childbirth, wherein the composition comprises sodium polyacrylate (see col. 5, lines 40-41). The Examiner acknowledges that sodium polyacrylate is not present as a lubricant, but cites JP '256 as disclosing that sodium (or ammonium) polyacrylate is useful as a lubricant during birth. Applicants respectfully disagree.

JP '256 is directed to a lubricant consisting essentially of a polyacrylate and water. Applicants submit that JP '256 is directed exclusively to a lubricant for use in veterinary medicine (see title of JP '256). Due to the significant differences between human and animal delivery, a person skilled in the art would not have been motivated to

employ a veterinary lubricant, i.e. the one disclosed in JP '256, for human vaginal childbirth as taught by Kasahara. This is also taught by the declarations signed by Prof. Saling and Prof. Litschigi submitted in response to the previous Office Action. Thus, Applicants submit that no combination of the cited art would have rendered obvious a method for reducing the frictional force between an item to be delivered and the birth canal of the mother in human vaginal child birthing, which comprises introducing a composition comprising a physiologically acceptable polyacrylic acid lubricant and no alkali metal salts of metaphosphates, wherein the composition is in the form of a paste, gel, cream, suppository or foam, in an effective amount into the birth canal of the woman. Applicants request that the rejection of claim 23 be withdrawn and the claim be allowed.

#### New Claims

New claims 24-27 have been added to define preferred embodiments of the invention. Support for new claim 24 can be found on page 7, paragraph 4 of the specification. Support for new claim 25 can be found on page 7, paragraph 2 of the specification. Support for new claims 26 and 27 can be found in the paragraph bridging pages 6 and 7, paragraph 2 on page 5, and paragraph 2 on page 7 of the specification.

#### Conclusion

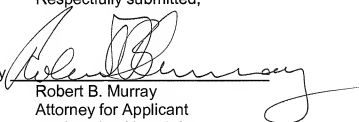
In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135. A Notice of Allowance is respectfully requested. Early

and favorable action is awaited.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

By

A handwritten signature in black ink, appearing to read "Robert B. Murray", is written over a horizontal line.

Robert B. Murray  
Attorney for Applicant  
Registration No. 22,980  
ROTHWELL, FIGG, ERNST & MANBECK  
1425 K. Street, Suite 800  
Washington, D.C. 20005  
Telephone: (202) 783-6040

RBM/AH  
1565007